MAY 10 2011

510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the Anterior Approach Hip Surgery Instruments.

(a)(1) Submitted By

Submitter's Name:

Wright Medical Technology, Inc.
5677 Airline Rd
Arlington, TN 38002
Phone: (901) 867-4350
Fax No: (901) 867-4190

Date: February 9, 2011

Contact Person: Matt Paul
Manager, Regulatory Affairs

(a)(2) Device Name

Proprietary Name: GLADIATOR® Plasma Classic Hip Stem.

Common Name: Hip Joint

Classification Name and Reference:

Class III - Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR 888.3330 - Product Code KWA).
Class III - Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21CFR 888.3320 - Product Code: JDL).
Class II – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353 - Product Code: LZO).

Subject Product Code and Panel Code: KWA, JDL, LZO. Orthopedics/87.

(a)(3) Predicate Device

Predicate Proprietary Name:

STEM Hip Replacement System - K021346.
PRO-FEMUR Hip System - K012091.
Metal TRANSCEND Articulation System – K004043.
PROFEMUR TL Hip Stem – K060358

Predicate Classification and Number:

Class III – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353 - Product Code: LZO).

Class III - Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis. (21CFR 888.3320 – Product Code: JDL).
Class III - Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis. (21CFR 888.3330 – Product Code: KWA).

(a)(4) Device Description

The GLADIATOR® Plasma Classic Hip Stem is a straight uncemented stem, and features a rectangular cross-section, proximally a trapezoidal section manufactured from base material of Titanium alloy (Ti6Al4V – ASTM F620, equivalent to ISO 5832-3). The profile tapers vertically both in frontal and lateral view, to achieve fixation stability in three planes. The stem possesses a 0.5mm thick titanium plasma spray coating on the proximal third of the stem surface, conforming to ASTM F1580. The stem length ranges from 125 mm to 175 mm in length, is available in 10 sizes (1-10), and features 0.5mm thick titanium plasma spray on the proximal third of the stem surface. The stem is available in standard and extended neck offsets.

(a)(5) Intended Use

The GLADIATOR® Plasma Classic Hip Stem is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

GLADIATOR® Plasma Classic Hip Stems are intended for use during uncemented hip arthroplasty.

(a)(6) Technological Characteristics of the Device

The GLADIATOR® Plasma Classic Hip Stem has the same technological characteristics as the predicate device. GLADIATOR® Plasma Classic Hip Stem is a straight uncemented hip stem with a monolithic design, possessing a fixed neck. It features a proximal trapezoidal cross-section and a distal rectangular cross-section. For fixation stability in three planes, the stem has a vertically tapered profile in the frontal and lateral planes. The materials used for the GLADIATOR® Plasma Classic Hip Stem are identical to the materials used for the predicate devices.

(b)(1) Nonclinical Testing

Brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:

The GLADIATOR® Plasma Classic Hip Stem has been tested in distal and proximal fatigue evaluation per the loading regimen prescribed by ISO 7206-4, -6 and -8.

The range of motion was evaluated for GLADIATOR® Plasma Classic Hip Stem according to ISO 21535 (2007).

(b)(2) Clinical Testing

Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:

Clinical data was not provided for the class III hip stem.

(b)(3) Conclusions

The indications for use of the GLADIATOR® Plasma Classic Hip Stem are identical to the previously cleared predicate devices. The design features of the subject device are substantially equivalent to the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the GLADIATOR® Plasma Classic Hip Stem are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology Inc.
% Mr. Matt Paul
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

MAY 10 2011

Re: K110399
Trade/Device Name: GLADIATOR® Plasma Classic Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LZO
Dated: February 9, 2011
Received: February 11, 2011

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110399

Indications for Use

510(k) Number (if known):

Device Name: **GLADIATOR® Plasma Classic Hip Stem**

The GLADIATOR® Plasma Classic Hip Stem is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

GLADIATOR® Plasma Classic Hip Stems are intended for use during uncemented hip arthroplasty.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

K110399

510(k) Number February 9, 2011